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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,280	01/20/2004	Joanne Peart	02940086CA	6861
30743 7590 01/25/2008 WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C. 11491 SUNSET HILLS ROAD SUITE 340 RESTON, VA 20190				
			EXAMINER ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 01/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/759,280

Applicant(s)

PEART ET AL.

Examiner

James H. Alstrum-Acevedo

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43, 46-48, 50, 52-55, and 57-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43, 46-48, 50, 52-55, and 57-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/11/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 43, 46-48, 50, 52-55, and 57-60 are pending. Applicants had previously cancelled claims 1-42, 44-45, 49, 51, and 56. Claims 57-60 are new. Receipt and consideration of Applicant's new IDS (submitted 10/11/07), amended claim set, declaration of Dr. Joanne Peart filed under 37 CFR 1.132, and arguments/remarks submitted on November 7, 2007 are acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 43, 46-48, 50, 53-55, and 57-60 under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804,592) in view of McNally et al. (U.S. Patent No. 5,653,961) **is maintained** for the reasons of record set forth in the office action mailed on December 28, 2005. New claims 61-63 are appended to this rejection for the reasons of record. In summary, **claims 43, 46-48, 50, 53-55, and 57-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804,592) in view of McNally et al. (U.S. Patent No. 5,653,961) for the reasons of record and further articulated below.**

The rejection of claim 52 under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804,592) in view of McNally et al. (U.S. Patent No. 5,653,961) as applied to 43, 46-48, 50, 51, and 53-55 above, and further in view of Pars et al. (U.S. Patent No. 3,728,360) **is maintained** for the reasons of record set forth in the office action mailed on December 28, 2005.

Response to Arguments

Applicant's arguments filed November 7, 2007 have been fully considered but they are not persuasive. Applicants have traversed the above outstanding rejections made under 35 U.S.C. §103(a) by (1) attacking the Mechoulam reference individually without addressing the merits of

the teachings of the combined prior art; (2) asserting that Applicants have presumably rebutted any allegation of the operability of Mechoulam based in part on the Peart declaration submitted on November 7, 2007, which tested the viability of peanut oil as an aerosol carrier for THC as was exemplified in Mechoulam for the oral non-inhalation administration of THC to mice; and (3) implicitly arguing that the rejections are improper under 35 U.S.C. §103(a) because the primary references do not exemplify methods of treatment utilizing non-CFC aerosols (i.e. the references are allegedly inappropriate because these do not anticipate the claimed invention).

The Examiner respectfully disagrees with Applicants' traversal arguments. In response to applicant's arguments (1)/ (3) against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants have failed to consider the teachings of the combined prior art references, and especially the explicit/implicit teachings and suggestions of the various cited prior art references. Applicants' argument (2) hinges on their experiments evaluating the effectiveness of peanut oil as an aerosol carrier, because, according to Applicants, Mechoulam's example for the oral non-inhalation administration of THC dissolved in peanut oil represents the closest prior art. Applicants averred that their experiments presented in declaration format demonstrated that peanut oil is not a viable aerosol carrier.

The Examiner respectfully disagrees with Applicants that Mechoulam's exemplified oral non-inhalation administered peanut oil/THC composition represents the closest prior art. Mechoulam was relied upon for its suggestion that THC could be administered as an aerosol by

inhalation. As a result, the evaluation of an oral non-inhalation administration vehicle is not an appropriate comparison. Furthermore, it appears Applicants have overlooked the cited teachings of Volicer, an alternative primary reference of the instant rejection, which clearly suggests that dronabinol (i.e. delta-9 THC) can be administered via inhalation by placement into pressurized acceptable propellants, such as propane, nitrogen, dichlorodifluoromethane, and the like (col. 5, lines 3-8). It is also noted that the instant rejection is based upon a combination of references. The secondary reference, McNally, clearly provides a motivation for substituting CFC propellants for hydrofluoroalkane propellants and indicates that it is conventional to utilize ethanol, a known cosolvent, to enhance the solubility of hydrophobic active agents. It is well within the capability of an ordinary skilled artisan to adjust the amount of ethanol in an HFA formulation to obtain a solution. Applicants have not provided evidence as to why an ordinary skilled artisan would be unable to modify or incapable of modifying the amount of ethanol in a hydrofluoroalkane formulation to obtain solution formulations of delta-9 THC, a hydrophobic medicament. It is noted that in Applicants' arguments, Applicants cited Davies (US 2005/0061314) and Whittle (US 2004/0192760) to buttress their arguments. However, both Davies and Whittle indicate that it was recognized as being conventional or advantageous in the art to add cosolvents to solubilize lipophilic cannabinoids (see paragraphs 34-35 in Davies and paragraph 66 in Whittle). Thus, these citations do not support Applicants' arguments. With regards to the rejection of claim 52, it is noted that Pars' THC-ester salts are taught as being capable of being hydrolyzed in vivo to yield the corresponding phenolic compound (i.e. the unesterified THC). As a result, Pars' ester salts represent functional equivalents of salts of unesterified THC and are suggestive of formulations comprising salts of unesterified THC.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

The rejection of claims 43, 48, 50, 52-55, and 57-60 under 35 U.S.C. 103(a) as being unpatentable over Pars et al. (U.S. Patent No. 3,728,360) in view of McNally et al. (U.S. Patent No. 5,653,961) **is maintained** for the reasons of record set forth in the office action mailed on December 28, 2005. New claims 61-63 are appended to this rejection for the reasons of record. In summary, **claims 43, 48, 50, 52-55, and 57-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pars et al. (U.S. Patent No. 3,728,360) in view of McNally et al. (U.S. Patent No. 5,653,961).**

Response to Arguments

Applicant's arguments filed November 7, 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection as being improper because Pars does not exemplify THC aerosol formulations or to suggest that the invented formulations are aerosolizable. Applicants' arguments are respectfully found unpersuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants have failed to consider the teachings of the combined prior art references, and especially the explicit/implicit teachings and suggestions of

the various cited prior art references. Specifically, an ordinary skilled artisan cognizant of Pars teachings that the invented ester derivatives and salts thereof of delta-9, delta-8, delta-6 THC compounds are soluble in aqueous ethanolic formulations would have a reasonable expectation that these THC ester derivatives and salts thereof are soluble in HFA formulations comprising ethanol, due to the presence of ethanol in amounts up to 20% w/w. Furthermore, it is noted that Pars' THC-ester salts are taught as being capable of being hydrolyzed in vivo to yield the corresponding phenolic compound (i.e. the unesterified THC). As a result, Pars' ester salts represent functional equivalents of salts of unesterified THC and are suggestive of formulations comprising salts of unesterified THC.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 43, 46, 48, 50, 52-55, and 57-60 are on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,509,005 (USPN '005) **is maintained** for the reasons of record set forth in the office action mailed on December 28, 2005. **New claims 61-63 are appended to this rejection** for the reasons of record.

Response to Arguments

In Applicant's remarks filed November 7, 2007, stated that a terminal disclaimer would be forthcoming once the art rejections were removed. No terminal disclaimer has been filed, thus the instant rejection is maintained.

The rejection of claims 43, 46-48, 50, 52-55, and 57-60 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 13-14, and 16 of U.S. Patent No. 6,713,048 (USPN '048) **is maintained** for the reasons of record. **New claims 61-63 are appended to this rejection** for the reasons of record.

Response to Arguments

In Applicant's remarks filed November 7, 2007, stated that a terminal disclaimer would be forthcoming once the art rejections were removed. No terminal disclaimer has been filed, thus the instant rejection is maintained.

Conclusion

Claims 43, 46-48, 50, 52-55, and 57-63 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

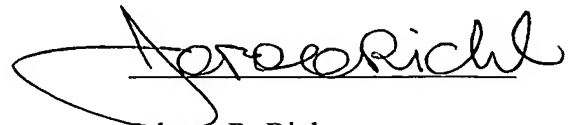
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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